

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***  
**40279**

**CORRESPONDENCE**

ANDA 40-279

Fujisawa, USA, Inc.  
Attention: Laurence R. Meyerson, Ph.D.  
3 Parkway North, 3rd Floor  
Deerfield, IL 60015- 2548

|||||

OCT 27 1997

Dear Sir:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Fluorouracil Injection USP, 50 mg/mL, 10 mL and 20 mL vials

DATE OF APPLICATION: October 3, 1997

DATE OF RECEIPT: October 6, 1997

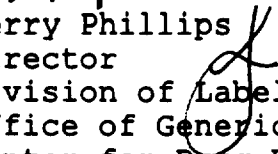
We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Sheila O'Keefe  
Project Manager  
(301) 827-5848

Sincerely yours,

  
Jerry Phillips  
Director  
Division of Labeling and Program Support  
Office of Generic Drugs  
Center for Drug Evaluation and Research



**FUJISAWA USA, Inc.**  
Parkway North Center, Three Parkway North  
Deerfield, Illinois 60015-2548  
Tel. (847) 317-8800 • Telefax (847) 317-7286

# Fujisawa

October 3, 1997

Douglas Sporn, Director  
Office of Generic Drugs  
Metro Park North II, HFD-600, Room 150  
Center for Drug Evaluation and Research  
Food and Drug Administration  
7500 Standish Place  
Rockville, MD 20855-2773

Labeling review completed

11/4/97

**Re: Fluorouracil Injection, USP**  
**50 mg/mL in 10 mL and 20 mL**  
**Glass Vials**  
**Manufacturing Site: Melrose Park, IL**  
**Number of Volumes: 2**

Dear Mr. Sporn:

This application is being submitted, in duplicate, as an Abbreviated New Drug Application in accordance with Title I, Sec. 101. Section 505(j) of the Federal Food, Drug and Cosmetic Act to seek marketing clearance for Fluorouracil Injection, USP. Enclosed, for your conveniences, are three copies of the analytical methods and validation section for the drug substance and finished dosage form.

Fujisawa USA, Inc. will manufacture this product at 2020 Ruby Street, Melrose Park, IL 60160. This application contains all the information required describing the manufacturing and control of Fluorouracil Injection, USP 50 mg/mL (10 mL and 20 mL vials), using 6720GC stopper. Since this is a sterile parenteral product, this application contains product specific sterile validation. Applicable general procedural approaches/data may be cross-referenced to Fujisawa USA, Inc., DMF. In addition, this application contains a request for the waiver of *in vivo* bioequivalence studies.

This application has been formatted according to the information in Office of Generic Drugs Policy and Procedure Guide #30-91, April 10, 1991 and letters to industry dated October 14, 1994 and December 24, 1996.

**RECEIVED**

**OCT 06 1997**

**GENERIC DRUGS**

**Fluorouracil Injection, USP**

**October 3, 1997**

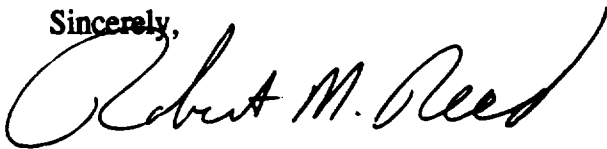
**Page Two**

An archival and review copy of this submission are provided for your review. Furthermore, a field copy has been sent to Mr. Raymond V. Mlecko, District Director, Chicago District, Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, Chicago, Illinois 60606 in accordance with 21 CFR §314.94(d)(5). Fujisawa USA, Inc. certifies that the field copy is a true copy of the Abbreviated New Drug Application herewith submitted.

Please be advised that an application for Pharmacy Bulk Package (PBP) is being submitted at the same time as the Single Dose Vial application.

Should you have any questions or require additional information concerning this application, please do not hesitate to contact the undersigned at (847) 317-8985 or Laurence Meyerson, Ph.D. at (847) 317-8642. The facsimile number is (847)317-7286.

Sincerely,



Robert M. Reed  
Manager, Regulatory Affairs

L:\WP60\ANDA\08.467

**RECEIVED**  
**OCT 06 1997**  
**GENERIC DRUGS**

June 3, 1998

Douglas Sporn, Director  
Office of Generic Drugs  
Metro Park North II, HFD-600, Room 150  
Center for Drug Evaluation and Research  
Food and Drug Administration  
7500 Standish Place  
Rockville, MD 20855-2773

NEW CORRESP

NC  
NAI  
JH 6/8/98

**RE: ANDA 40-279**  
**Fluorouracil Injection, USP**  
**50 mg/mL in 10 mL and 20 mL**  
**Single Dose vials**  
**Manufacturing Site: Melrose Park, IL**

**INTENT TO FILE A FACSIMILE AMENDMENT**

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application submitted on October 3, 1997 for the above mentioned drug product. Reference is also made to the FDA facsimile dated May 28, 1998. In accordance with 21 CFR 314.120(a)(1), American Pharmaceutical Partners, Inc. is informing you of our **intent to file a facsimile amendment** in response to this facsimile in the near future. Please note that the ownership of this application had been transferred from Fujisawa USA, Inc. to American Pharmaceutical Partners, Inc. effective June 1, 1998.

Should you have any questions or require additional information concerning this application, please contact the undersigned at (708) 547-3617 or Mitchall G. Clark at (310) 264-7768.

Sincerely,

*Lincy Michael*

Lincy Michael  
Senior Regulatory Scientist

**RECEIVED**

**JUN 04 1998**

**GENERIC DRUGS**

*Madame  
6-5-98*

ARCHIVAL



**Fujisawa USA, Inc.**

Parkway North Center, Three Parkway North  
Deerfield, Illinois 60015-2548

Telephone (847) 317-8800 • Telefax (847) 317-7286

Fujisawa

June 1, 1998

Douglas Sporn, Director  
Office of Generic Drugs  
Food and Drug Administration  
Center for Drug Evaluation and Research  
HFD-600, Room 150  
7500 Standish Place  
Rockville, MD 20855-2773

NEW CORRESP

CC

*Handwritten signature/initials*

RE: ANDA 40-279  
Fluorouracil Injection, USP (Single Vial Dose)  
Pending Approval

**CHANGE IN OWNERSHIP OF AN APPLICATION**

Dear Mr. Sporn:

In accordance with the provisions of 21 CFR 314.72, the ownership of the above identified ANDA is being transferred in its entirety, effective June 1, 1998, from Fujisawa USA, Inc. (FUSA) to American Pharmaceutical Partners, Inc (APP).

FUSA affirms that all of the rights to the referenced ANDA have been transferred to APP and that a complete copy of the ANDA including all amendments and FDA correspondence have been provided to APP.

The name and address of the new primary contact person at APP is:

CORPORATE ADDRESS

Mitchall Clark  
Senior Director, Regulatory Affairs  
American Pharmaceutical Partners, Inc.  
2825 Santa Monica Boulevard  
Santa Monica, CA 90404  
Phone: (310)264-7768

CORRESPONDENCE ADDRESS

Mitchall Clark  
Senior Director, Regulatory Affairs  
American Pharmaceutical Partners, Inc.  
2045 N. Cornell Avenue  
Melrose Park, IL 60160  
Phone: (708)343-6100

All FDA correspondence should be forwarded to the correspondence address.

Please change your records to reflect this change in the ownership of the ANDA and acknowledge receipt of this letter. All future communications regarding this ANDA should be sent to APP.

Sincerely,

Jerry D. Johnson, Ph.D.

Vice President, Regulatory Affairs and Pharmacovigilance

cc: Mitchall Clark  
Senior Director, Regulatory Affairs (APP)

RECEIVED

JUN 02 1998



**FUJISAWA USA, Inc.**  
Parkway North Center, Three Parkway North  
Deerfield, Illinois 60015-2548  
Tel. (847) 317-8800 • Telefax (847) 317-7286

**ARCHIVAL**  
**Fujisawa**

May 13, 1998

Douglas Sporn, Director  
Office of Generic Drugs  
Metro Park North II, HFD-600, Room 150  
Center for Drug Evaluation and Research  
Food and Drug Administration  
7500 Standish Place  
Rockville, MD 20855-2773

**ORIG AMENDMENT**  
N/FA

**RE: ANDA 40-279**  
**Fluorouracil Injection, USP**  
**50 mg/mL in 10 mL and 20 mL vials**

**TELEPHONE AMENDMENT**

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application submitted on October 3, 1997 for the above mentioned drug product. References are also made to the facsimile amendment submitted to the FDA on April 30, 1998 and the telephone conversation between Carol Holquist (FDA) and Lincy Michael (Fujisawa) on 5/12/98. As requested by Ms. Holquist, we are sending additional copies of the carton labels.

As discussed on pages 000 00043 and 000 00045 of our facsimile amendment dated April 30, 1998, the 10 mL and 20 mL vials will be packaged in unprinted trays. Each unprinted tray will be properly identified by attaching a vial label to it during the product packaging process. Additionally, the tray will be marked with the quantity of vials per tray. The 10 mL and 20 mL labels included in this submission represent the container and carton labels which should replace pages 000 00067 and 000 00068 of the facsimile amendment dated April 30, 1998.

In compliance with 21 CFR 314.96(b), a true and complete field copy of this amendment is being submitted to Mr. Raymond V. Mlecko, District Director, Chicago District, Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Should you require additional information concerning this application, please contact the undersigned at (708) 547-3617 or Laurence R. Meyerson, Ph.D. at (847) 317-8642.

Sincerely,

Lincy Michael  
Senior Regulatory Scientist

**RECEIVED**

**MAY 14 1998**

**GENERIC DRUGS**



**FUJISAWA USA, Inc.**  
Parkway North Center, Three Parkway North  
Deerfield, Illinois 60015-2548  
Tel. (847) 317-8800 • Telefax (847) 317-7288

# Fujisawa

April 30, 1998

Douglas Sporn, Director  
Office of Generic Drugs  
Metro Park North II, HFD-600, Room 150  
Center for Drug Evaluation and Research  
Food and Drug Administration  
7500 Standish Place  
Rockville, MD 20855-2773

**REVIEW**

**RE: ANDA 40-279**  
**Fluorouracil Injection, USP**  
**50 mg/mL in 10 mL and 20 mL vials**  
**Manufacturing Site: Melrose Park, IL**

## **FACSIMILE AMENDMENT**

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application submitted on October 3, 1997 for the above mentioned drug product. References are also made to the attached facsimile dated March 31, 1998 and the telephone conversations between Sheila O'Keefe (FDA) and Lincy Michael (Fujisawa) on 4/3/98 and 4/14/98. We are responding to the observations noted in the facsimile and hereby submit this facsimile amendment. For ease of review, we have organized the FDA observations with the corresponding Fujisawa USA, Inc. responses in the order as delineated in the letter.

As discussed during the telephone conversation on 4/14/98 with Ms. O'Keefe, the ownership of this application will be transferred to American Pharmaceutical Partners, Inc. (APP) on or about June 1, 1998. It is our intent to market this product under APP upon approval. The Final Printed Labeling which is included in this submission reflects APP's name. A letter certifying the change in ownership of this application will be submitted to the FDA when the change occurs.

In compliance with 21 CFR 314.96(b), a true and complete field copy of this amendment is being submitted to Mr. Raymond V. Mlecko, District Director, Chicago District, Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

**RECEIVED**

**MAY 01 1998**

**GENERIC DRUGS**



Douglas Sporn, Director  
ANDA 40-279  
Fluorouracil Injection, USP  
April 30, 1998

Page 2

Should you have any questions or require additional information concerning this application, please contact the undersigned at (708) 547-3617 or Laurence R. Meyerson, Ph.D. at (847) 317-8642.

Sincerely,

A handwritten signature in black ink that reads "Lincy Michael". The signature is written in a cursive style with a large, looping "L" and a long, sweeping "M".

Lincy Michael  
Senior Regulatory Scientist

5-FU-1-4/3/98



July 16, 1998

Douglas Sporn, Director  
Office of Generic Drugs  
Metro Park North II, HFD-600, Room 150  
Center for Drug Evaluation and Research  
Food and Drug Administration  
7500 Standish Place  
Rockville, MD 20855-2773

ANDA 40-279  
N/AM

**RE: ANDA 40-279**  
**Fluorouracil Injection, USP**  
**50 mg/mL in 10 mL and 20 mL vials**  
**Manufacturing Site: Melrose Park, IL**

**MINOR AMENDMENT**

Dear Mr. Sporn:

Reference is made to our Abbreviated New Drug Application submitted on October 3, 1997 for the above mentioned drug product. References are also made to the attached facsimile dated May 28, 1998 and the telephone conversation between Ms. Denise Huie (FDA), Mr. Jim McVey (FDA) and Ms. Lincy Michael (American Pharmaceutical Partners, Inc.) on 6/23/98. We are responding to the observations noted in the facsimile and hereby submit this minor amendment. For ease of review, we have organized the FDA observations with the corresponding responses in the order as delineated in the letter.

Please note that the ownership of this application was transferred from Fujisawa USA, Inc. to American Pharmaceutical Partners, Inc. (APP) effective June 1, 1998. A letter notifying this ownership transfer was sent to the FDA on June 2, 1998.

In compliance with 21 CFR 314.96(b), a true and complete field copy of this amendment is being submitted to Mr. Raymond V. Mlecko, District Director, Chicago District, Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Should you have any questions or require additional information concerning this application, please contact the undersigned at (708) 547-3617.

Sincerely,

Lincy Michael  
Senior Regulatory Scientist

**RECEIVED**

**JUL 20 1998**

**GENERIC DRUGS**

2045 NORTH CORNELL  
MELROSE PARK, ILLINOIS 60160

TEL (708) 343-6100  
FACSIMILE (708) 343-4269  
WWW.AMPHARMAPARTNERS.COM

*Handwritten:*  
Lincy Michael  
7/22/98